

Replacement Sheet

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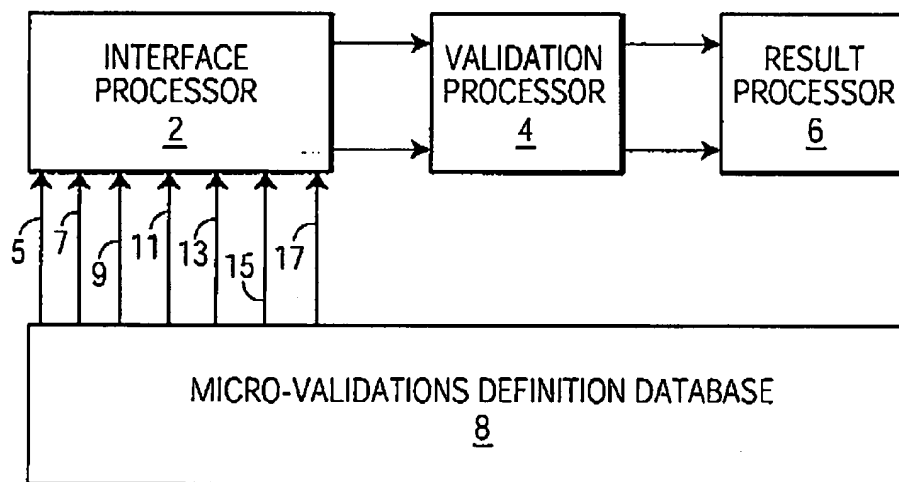
100

FIG. 1

Replacement Sheet

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232a

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232d

232h

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NOVIUS Lab LDT's

File Record Edit Window Help

Micro Validation Definitions: Organism

Test: GRAM

Perf Instr: ETYPE

Result: IN GNRGRP

Org Grp Prior: 8

Active: ACTIV

Culture Test: IN CBLD

Source: *

Validation Desc: Organism Id does not correlate to the GramStain result

Validation Fail Msg: VLDGSS

Override Cntrl Req?: ☐

Incubation Time: 1

Expected Results

| TEST | ORG ID | RESULT | IN | GNRGRP | Req? |
|------|--------|--------|----|--------|--|
| 1 | TEST | ORG ID | IN | GNRGRP | <input checked="" type="checkbox"/> Req? |
| 2 | TEST | RESULT | * | | <input type="checkbox"/> Req? |
| 3 | TEST | RESULT | * | | <input type="checkbox"/> Req? |
| 4 | TEST | RESULT | * | | <input type="checkbox"/> Req? |
| 5 | TEST | RESULT | * | | <input type="checkbox"/> Req? |
| 6 | TEST | RESULT | * | | <input type="checkbox"/> Req? |
| 7 | TEST | RESULT | * | | <input type="checkbox"/> Req? |
| 8 | TEST | RESULT | * | | <input type="checkbox"/> Req? |

RECORD: 5 of 5

Form View

FIG. 2

Replacement Sheet

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| 30 | 32 | 34 |
|-----------------------|-------------------------------|--|
| FIELD IN THE UDT FORM | DESCRIPTION | CORRESPONDING dB COLUMN |
| 208 | TEST | DISPLAYS THE TEST THAT IS BEING VALIDATED |
| 210 | PERF INSTITUTION | SELECT THE PERFORMING INSTITUTION WHERE THIS VALIDATION WILL BE EVALUATED. |
| 226 | VALIDATION SEVERITY | SELECT INFO, WARN, OR FAIL |
| 228 | OVERRIDE CMNT REQ? | SELECT THIS WHEN A REASON FOR OVERRIDE COMMENT IS REQUIRED |
| 212 | RESULT | SELECT * (ANY), IN, NI, OR = ENTER THE RESULT THAT WILL INDICATE WHEN THE VALIDATION WILL BE EVALUATED |
| 214 | ORG GRP PRIO | VALUE ENTERED BASED ON THE PRIORITY DEFINED IN THE ORGANISM GROUP UDT. |
| 218 | CULTURE TEST | ENTER THE CULTURE TEST(S) THAT WILL BE TAKEN INTO CONSIDERATION WHEN DETERMINING IF THIS VALIDATION SHOULD BE EVALUATED. |
| 220 | SOURCE | ENTER THE SOURCE(S) THAT WILL BE TAKEN INTO CONSIDERATION WHEN DETERMINING IF THIS VALIDATION SHOULD BE EVALUATED. |
| 222 | VALIDATION DESCRIPTION | ENTER A DESCRIPTION (250 CHARACTER MAX), THAT SPECIFICALLY DESCRIBES THIS VALIDATION |
| 224 | VALIDATION FAIL MSG | SELECT THE CODED TEXT DEFINED IN THE CODED TEXT ID UDT (UNLIMITED LENGTH). |
| 230 | INC TIME | ENTER A NUMERAL TO REPRESENT THE NUMBER OF DAYS A CULTURE MUST BE INCUBATED BEFORE THIS VALIDATION WILL BE EVALUATED. |
| 234 | EXPECTED RESULTS TEST (1 - 9) | ENTER THE TEST ID THAT IS BEING COMPARED TO VALIDATED TEST. HAVE THE ABILITY TO ENTER UP TO 9 DIFFERENT TESTS AND EXPECTED RESULTS. |
| 236 | RESULT (1 - 9) | SELECT * (ANY), IN, NI, OR = ENTER THE RESULTS THAT ARE EXPECTED FOR THE TEST. HAVE THE ABILITY TO ENTER UP TO 9 DIFFERENT TESTS AND EXPECTED RESULTS. |
| 238 | REQ? | SELECT THIS WHEN THE TEST AND THE RESULT IS REQUIRED. HAVE THE ABILITY TO DEFINE UP TO 9 |

FIG. 3

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FIG. 4

411 418 415 417 419

Workcard View - C BLD(PRELIM)

Workcard Edit View Options Help

7200 09/26/2003 12:33 BLD UNKNOWN DOCTOR ND

DILLOW RALIEGH 342525 M 42 09/26/2003 12:33

Direct Exam Add Test Enter Result

Test ID Rslt

* MEDIA PERFORMED

Culture Workup NG NP NF 24H 48H 72H Enter Result Add/Edit Org View Suscept

Test Id Org # Result Test/Biochem Rslt Tech Notes

CULT RPT

Comp/Save Rel/Save Rel/Fin/Save Comp/Fin/Save Search Close Help

Ready Micro

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FIG. 5a

Workcard View - C BLD(PRELIM)

Workcard Edit View Options Help

7200 09/26/2003 12:33 BLD UNKNOWN DOCTOR ND

DILLOW RALIEGH 342525 M 42 09/26/2003 12:33

Direct Exam Add Test Enter Result

| Test ID | Rslt | Rslt Sys | Sys D/T |
|---------|-------------------------|----------|---------|
| * GRAM | MANY GRAM NEGATIVE RODS | ENT | 09/26/2 |
| * MEDIA | PERFORMED | ENT | 09/26/2 |

Culture Workup NG NP NF 24H 48H 72H Enter Result Add/Edit Org View Suscept

| Test Id | Org # | Result | Test/Biochem RsLt | Tech Notes |
|----------|-------|--------|-------------------|------------|
| CULT RPT | | | | |

Comp/Save Rel/Save Rel/Fin/Save Comp/Fin/Save Search Close Help

Ready Micro

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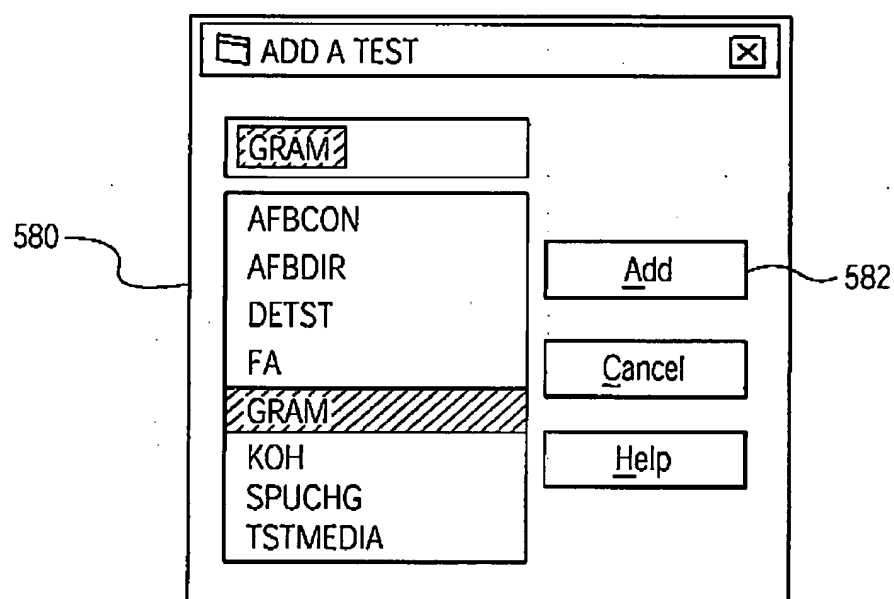
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FIG. 5b

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Enter Result

☒ Coded Text ☐ Free Text

Quan: MANY Desc: GNR

| | |
|---------|---------|
| m<10 | EPI |
| FEW | GNDC |
| LOQUANT | GNDC |
| MANY | GNDC |
| MOD | GNR |
| NO/ | GNRPLEO |
| RARE | GPR |
| | GPRD |
| | HYPHAE |
| | LDERSLT |
| | LONG |

ADD REMOVE

Coded Text Result:

MANY GRAM NEGATIVE RODS

Apply Close Help

FIG. 5C

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FIG. 5d

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Organism Info ORG 1 NEW

Tech Notes

Coded Text ID:

Test

Biochemicals

Test

Result:

CAT

TUBE

Result Free Text:

Organisms

Quantity:

Org ID:

Org Rslt

Comment

Apply

Prev Org

Next Org

Suscept

Close

Help

| TEST ID | RESULT |
|---------|----------|
| * CAT | POSITIVE |
| * TUBE | POSITIVE |

| Org Rslt | Comment |
|------------------------------|---------|
| * MANY STAPHYLOCOCCUS AUREUS | |

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FIG. 6

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Workcard View - C BLD(PRELIM)

Workcard Edit View Options Help

7200 09/26/2003 12:33 BLD UNKNOWN DOCTOR ND

DILLOW RALIEGH 342525 M 42 09/26/2003 12:33

Direct Exam Add Test Enter Result

| Test ID | Rslt | Rslt Sis | Sis D/T |
|---------|-------------------------|----------|---------|
| * GRAM | MANY GRAM NEGATIVE RODS | ENT | 09/26/2 |
| * MEDIA | PERFORMED | ENT | 09/26/2 |

Culture Workup NG NP NF 24H 48H 72H Enter Result Add/Edit Org View Suscept

| Test Id | Org # | Result | Test/Biochem Rslt | Tech Notes |
|----------|-------|----------------------------|-------------------|------------|
| * ORG ID | 1 | MANY STAPHYLOCOCCUS AUREUS | | |

Comp/Save Rel/Save Rel/Fin/Save Comp/Fin/Save

Ready Micro

Replacement Sheet

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Validation Failure Window

Enter Reason For Override

| Validation Severity | Validation Test ID/Result | Failed Test ID/Result | User Message | Expected Result | Requires Comment? | Reason to Override |
|---------------------|---------------------------|-------------------------------|---|-----------------------------|-------------------|--------------------|
| FAIL | 704 GRAM/ MANY GNR | 706 ORG ID/ MANY STAAUR | 708 Gram stain does not match the orgs released. Reconfirm Gram stain. | 710 ORG ID/ IN GNRGRP | 712 N | 714 |

Do you want to override the validation failure and continue with Release?

Yes No Help

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FIG. 7a

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The image shows a graphical user interface window. The title bar at the top contains a close button (X) and the text "Add Reason for Override". The main content area is labeled "Reason:" and contains a text input field with the text "I re-checked the gram stain and organism.". At the bottom right of the window, there are three buttons: "Add", "Close", and "Help".

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FIG. 7b

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FIG. 8

Workcard View - C BLD(PRELIM)

Workcard Edit View Options Help

7200 09/26/2003 12:33 BLD UNKNOWN DOCTOR ND

DILLOW RALIEGH 342525 M 42 09/26/2003 12:33

Direct Exam Add Test Enter Result

| | | | |
|---------|-------------------------|----------|---------|
| Test ID | Rslt | Rslt Sts | Sts D/T |
| MEDIA | PERFORMED | ENT | 09/26/2 |
| GRAM | MANY GRAM NEGATIVE RODS | ENT | 09/26/2 |

Culture Workup NG NP NF 24H 48H 72H Enter Result Add/Edit Org View Suscept

| | | | |
|----------------------------|-------------------|------------|----------|
| Result | Test/Biochem Rslt | Tech Notes | Rslt Sts |
| MANY STAPHYLOCOCCUS AUREUS | CAT:P; TUBE:P | | PEND |
| | | | ENT |

Comp/Save Rel/Save Rel/Fin/Save Comp/Fin/Save Search Close Help

Ready Micro

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FIG. 9

Workcard View - C BLD(PRELIM)

Workcard Edit View Options Help

7200 09/26/2003 12:33 BLD UNKNOWN DOCTOR SIG

DILLOW RALIEGH 342525 M 42 09/26/2003 12:33

Direct Exam Add Test Enter Result

| | | | |
|---------|-------------------------|----------|---------|
| Test ID | Rslt | Rslt Sts | Sls D/T |
| MEDIA | PERFORMED | COMP | 09/26/2 |
| GRAM | MANY GRAM NEGATIVE RODS | COMP | 09/26/2 |

Culture Workup NG NP NF 24H 48H 72H Enter Result Add/Edit Org View Suscept

| | | | |
|----------------------------|-------------------|------------|----------|
| Result | Test/Biochem Rslt | Tech Notes | Rslt Sts |
| MANY STAPHYLOCOCCUS AUREUS | CAT:P; TUBE:P | | PEND |
| | | | COMP |

Comp/Save Rel/Save Rel/Fin/Save Comp/Fin/Save Search Close Help

Ready Micro

416 420 422 424 426

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Review Validation Window

| Validation Severity | Validation Description | Reason to Override |
|---------------------|--|---------------------------------------|
| FAIL | Gram Stain with Many or Mod GNR does not have a GNR reported | I re-checked the gram stain and organ |

Do you want to continue with the Review/Finalize action?

Yes No Help

1002 1004

FIG. 10